

REMARKS

Status of the Claims

Claims 197-205, 222-229, and 232-246 are currently pending in the present application. Claims 1-196, 206-221, 230, and 231 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Claims 197, 199, 222-229, 232-234, and 243 have been amended, and new claims 244-246, directed to the same invention as claims 197, 199, 202-205, 222-229, and 232-243, have been added.

Amendments to the Claims

The amendments to the claims and the addition of the new claims supply separate specific embodiments of the claimed invention. The amendments to claims 197, 202-205, 222-229, 232-234 and 243 and the addition of new claims 244-246 do not introduce prohibited new matter. Representative support for the amendments to the claims and the new claim is summarized in the table below.

Claim(s)	Support
197	Claim 199; Page 10, line 21
202-205, 233, 234, 243	Claim 199
222-229, 232, 233, 234, 243	Amended to delete dependencies to canceled claims and for consistency with the amendments to claim 197.
244, 245	Claims 197 and 201
246	Claim 198

Applicants note that the exclusionary limitation added to claim 197 is merely to help define the claimed invention from the prior art. As such, this limitation is not prohibited new matter. *In re Johnson and Farnham*, 194 USPQ 187, 196 (CCPA 1977).

Rejection of the Claims Under 35 U.S.C. § 102

A. Claims 197-201, 203-205, 234, 235, and 238-243 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson *et al.*

Claim 197 has been amended to be directed to a method of reducing the level of active biological contaminants or pathogens in solid tissue, comprising adding to the tissue at least two stabilizers selected from the group consisting of mannitol, trehalose, and DMSO and irradiating the plasma or serum with a dose of gamma radiation. Claim 197 has also been amended to exclude the addition of an extraneous protein to the tissue. Claims 199, 203-205, 234, 235, and 238-243 are dependent upon claim 197, and therefore, also include the negative limitation. Accordingly, claims 197, 199, 203-205, 234, 235, and 238-243 do not comprise adding an extraneous protein to the hard tissue.

In contrast, the method of Peterson requires the addition of an extraneous protein to the biologically active compound being irradiated. Accordingly, the reference of Peterson does not anticipate the claimed invention.

Applicants respectfully submit the cited references also do not anticipate the new claims. New claim 244 is ultimately dependent upon claim 197 and therefore includes all the limitations of claim 197. New claim 245 includes all the limitation recited in claim 197 and adds the limitation that the tissue is a specific soft tissue not taught by the cited references. New claim 246 includes all the limitation recited in claim 197 and adds the limitation that the tissue is a hard tissue.

B. Claims 217 and 219 are rejected under 35 U.S.C. § 102(b) as being anticipated by Horowitz *et al.*

Claims 217 and 219 have been canceled. Thus, the rejection is rendered moot.

Rejection of the Claims Under 35 U.S.C. § 103(a)

A. Claims 197, 200, 202-210, 227, 230, 234, 235, and 238-243 are rejected under 35 U.S.C. §103 (a) as being unpatentable over Freistedt *et al.* in view of Peterson.

Claim 230 has been canceled. As discussed above, claim 197 has been amended to be directed to a method of reducing the level of active biological contaminants or pathogens in solid tissue, comprising adding to the tissue at least two stabilizers selected from the group consisting of mannitol, trehalose, and DMSO and irradiating the plasma or serum with a dose of gamma

radiation. Claim 197 has also been amended to exclude the addition of an extraneous protein to the tissue. Claims 202-205, 227, 234, and 238-243, are dependent upon claim 197 and therefore include the limitations of claim 197.

Freistedt *et al.* do not teach a method of reducing the level of active biological contaminants or pathogens by adding to the tissue two or more stabilizers selected from the group consisting of mannitol, trehalose, and DMSO. Moreover, Freistedt *et al.* do not disclose adding mannitol or trehalose. Freistedt *et al.* only provide a generic disclosure of polyols and a few examples of specific polyols, such as glycol, triethylene glycol, erythritol, or pentitol, and/or DMSO.

Applicants respectfully point out that in *In re Baird*, the court held that a disclosure of a generic formula that may encompass claimed compound does not, without more render a specific compound obvious. *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). In *Baird*, the court found that a patent disclosing a generic diphenol formula encompasses various different diphenols in addition to the claimed bisphenol, did not render the claimed bisphenol obvious because the patent does not provide specific variables for picking the specific bisphenol. Similar to the facts in *In re Baird*, Freistedt *et al.* teach the addition of any polyols, but does not teach specifically selecting for mannitol or trehalose from the group of polyols and at least one other polyol. Thus, Freistedt *et al.* do not render the claimed invention obvious.

Peterson does not cure the deficiencies of Freistedt *et al.* As discussed above, Peterson requires the addition of an extraneous protein to the product prior to irradiation. Thus, the cited references do not provide the motivation necessary to modify the method of sterilization disclosed in the cited references to arrive at the method recited in the claims with reasonable expectation of success. Accordingly, the combination of the cited references does not render the claimed invention obvious.

Applicants respectfully submit the cited references also do not render the new claims obvious. New claim 244 is ultimately dependent upon claim 197 and therefore includes all the limitations of claim 197. New claim 245 includes all the limitation recited in claim 197 and adds the limitation that the tissue is a specific soft tissue not taught by the cited references. New claim

246 includes all the limitation recited in claim 197 and adds the limitation that the tissue is a hard tissue.

B. Claim 223 is rejected under 35 U.S.C. §103 (a) as being unpatentable over Peterson in view of Horowitz *et al.*

Claim 223 is dependent upon claim 197 and adds the limitation that the total dose of irradiation is 45 kGy. As discussed in detail above, claim 197 has been amended to recite a method of irradiating a solid tissue comprising adding two or more specific stabilizers selected from the group consisting of mannitol, trehalose, and DMSO and to exclude the addition of an extraneous protein to the product prior to irradiation.

Also, as discussed above, Peterson requires the addition of an extraneous protein to the product prior to irradiation. Applicants respectfully point out that the addition of an extraneous protein is excluded from the present invention.

The reference of Horowitz *et al.* is relied upon for disclosing irradiating with a typical dose of 40 kGy. However, the reference of Horowitz *et al.* does not cure the deficiency of Peterson because the reference of Horowitz *et al.* does not teach a method of irradiating solid tissue. The reference only teaches irradiating blood. Since the cited references disclose sterilizing different products by irradiation, there is no motivation to combine these cited references and modify the method of sterilization disclosed in them to obtain the method recited in the claims with reasonable expectation of success. Accordingly, the combination of the cited references does not render the claimed invention obvious.

C. Claims 224-226 are rejected under 35 U.S.C. §103 (a) as being unpatentable over Peterson or Horowitz *et al.* or Freistedt *et al.*

Claims 224-226 are dependent upon claims 197 and add the limitation that the stabilizer is present at a specific concentration. As discussed in detail above, claim 197 has been amended to recite a method of irradiating a solid tissue comprising adding two or more specific stabilizers selected from the group consisting of mannitol, trehalose, and DMSO and to exclude the addition of an extraneous protein to the product prior to irradiation (see Section A).

Also, as discussed above, Peterson teaches irradiating solid tissue but requires the addition of an extraneous protein to the product prior to irradiation. In contrast, the present invention excludes the addition of an extraneous protein.

The reference of Horowitz *et al.* is relied upon for disclosing the presence of stabilizers in conventional quenching amounts. However, as discussed above, Horowitz *et al.* do not teach irradiating solid tissue (see Section B).

The deficiencies of Freistedt *et al.* are discussed above (see Section A). Freistedt *et al.* do not disclose the amount of stabilizers used. Neither Horowitz *et al.* nor Freistedt *et al.* cure the deficiencies of Peterson, because Horowitz *et al.* only teach irradiating blood, and Freistedt *et al.* do not teach the required stabilizers recited in the claims. Accordingly, there is no motivation to combine these cited references and modify the method of sterilization disclosed in the cited references to obtain the method recited in the claims with reasonable expectation of success. Accordingly, the combination of the cited references does not render the claimed invention obvious.

D. Claims 220 and 221 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Horowitz *et al.* in view of Peterson.

Claims 220 and 221 have been canceled. Thus, the rejection is rendered moot.

E. Claims 206-216, 228, 233, 236, and 237 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson in view of Horowitz *et al.*

Claims 206-216 have been canceled. Claims 228, 233, 236, and 237 are dependent upon claims 197. Claim 228 adds the limitation that the stabilizer is mannitol. Claim 233 adds the limitation that the tissue is contacted with one or more sensitizers. Claims 236 and 237 add the limitation that the one or more residual solvents is an organic solvent.

As discussed above, Peterson teaches irradiating solid tissue but requires the addition of an extraneous protein to the product prior to irradiation. In contrast, the present invention excludes the addition of an extraneous protein.

The reference of Horowitz *et al.* is relied upon for disclosing polyhydric alcohols such as mannitol, as a stabilizer, adding a sensitizer to the product to be irradiated, and treating the product with organic solvent. However, the reference Horowitz *et al.* does not cure the deficiency of Peterson because Horowitz *et al.* do not teach a method of irradiating solid tissue. Horowitz *et al.* only teach irradiating blood. Since the cited references teach irradiating different products, there is no motivation to combine these cited references and modify the method of sterilization disclosed in them to obtain the method recited in the claims with reasonable expectation of success. Accordingly, the combination of the cited references does not render the claimed invention obvious.

F. Claim 218 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Horowitz *et al.* in view of Zabal *et al.*

Claim 218 has been canceled. Thus, the rejection is rendered moot.

G. Claim 222 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson or Freistedt *et al.* in view of Peterson as applied to claims 197 and 206 above and further in view of Chanderkar *et al.*

Claim 222 is dependent upon claim 197 and adds the limitation that the irradiation is applied at a rate of at least about 3.0 kGy/hour to at least about 30.0 kGy/hour. Claim 206 has been canceled.

The deficiencies of Peterson and Freistedt *et al.* are discussed above (see section A or C). The reference of Chanderkar *et al.* is relied upon for disclosing irradiation at a dose rate of 7.5 kGy/hr. However, Chanderkar *et al.* do not teach irradiating solid tissue at a dose rate of 7.5 kGy/hr. Chanderkar *et al.* only disclose irradiating fibrinogen, a protein, at this rate. Thus, Chanderkar *et al.* do not cure the deficiencies of Peterson and/or Freistedt *et al.* Accordingly, the cited references do not render the claimed invention obvious.

H. Claim 227 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson or Freistedt *et al.*

Claim 227 is dependent upon claim 197 and adds the limitation that the stabilizer is DMSO.

As discussed above, Peterson teaches irradiating solid tissue but requires the addition of an extraneous protein to the product prior to irradiation. In contrast, the present invention excludes the addition of an extraneous protein.

The reference of Freistedt *et al.* is relied upon for disclosing DMSO as a stabilizer. However, Freistedt *et al.* do not teach irradiating solid tissue in the presence of DMSO and mannitol or trehalose as required by the claims. The deficiencies of Freistedt *et al.* are discussed above in detail (see Section A). Freistedt *et al.* do not cure the deficiencies of Peterson. Thus, there is no motivation to combine the cited references and modify the disclosed prior art to obtain the claimed invention with reasonable expectation of success. Accordingly, the cited references do not render the claimed invention obvious.

I. Claim 229 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson or Peterson in view of Horowitz *et al.* as applied to claims 197 and 206 above and further in view of Okrongly *et al.*

Claim 229 is dependent upon claim 197 and adds the limitation that the stabilizer is trehalose. Claim 206 has been canceled.

The deficiencies of Peterson and Horowitz *et al.* are discussed in detail above (see section E). The reference of Okrongly *et al.* is relied upon for disclosing trehalose. However, Okrongly *et al.* do not teach irradiating solid tissue in the presence of trehalose. Okrongly *et al.* only teach irradiating macromolecules in the presence of trehalose. Thus, there is no motivation to combine the cited references and modify the disclosed prior art to obtain the claimed invention with reasonable expectation of success. Accordingly, the cited references do not render the claimed invention obvious.

Applicants note that Freistedt *et al.* is cited in the body of the rejection and point out that Freistedt *et al.* do not teach irradiating solid tissue in the presence of trehalose.

J. Claims 231 and 232 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Freistedt *et al.* in view of Peterson as applied to claims 197 and 206 above and further in view of Okrongly *et al.*

Claims 206 and 231 have been canceled. Claim 232 is dependent upon claim 197 and adds the limitation that the stabilizers are DMSO and mannitol.

The deficiencies of Peterson are discussed in detail above (see section G). The reference of Freistedt *et al.* is relied upon for teaching the combined use of DMSO and a polyol as radioprotectants during irradiation of soft tissue. However, Freistedt *et al.* do not teach adding DMSO and mannitol (see Section A). The reference of Okrongly *et al.* is relied upon for disclosing mannitol and trehalose. However, Okrongly *et al.* do not teach irradiating solid tissue in the presence of mannitol or trehalose. Okrongly *et al.* only teach irradiating macromolecules in the presence of mannitol or trehalose. Thus, there is no motivation to combine the cited references and modify the disclosed prior art to obtain the claimed invention with reasonable expectation of success. Accordingly, the cited references do not render the claimed invention obvious.

K. Claim 233 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Freistedt *et al.* in view of Peterson as applied to claims 197 and 206 above and further in view of Horowitz *et al.*

Claim 233 is dependent upon claim 197 and adds the limitation that a sensitizer is added to the hard tissue. Claim 206 has been canceled.

The deficiencies of Freistedt *et al.* and Peterson are discussed in detail above (see section G). Neither reference discloses adding sensitizers to the product to be irradiated. The reference of Horowitz *et al.* is relied upon for disclosing adding a sensitizer prior to irradiation. However, Horowitz *et al.* do not teach irradiating solid tissue in the presence of a sensitizer. Horowitz *et al.* only teach irradiating blood in the presence of a sensitizer. Thus, there is no motivation to combine the cited references and modify the disclosed prior art to obtain the claimed invention with reasonable expectation of success. Accordingly, the cited references do not render the claimed invention obvious.

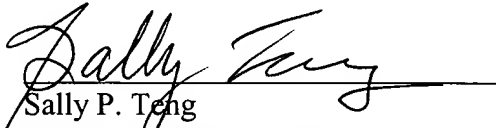
Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
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